

Notice of Allowability	Application No.	Applicant(s)	
	09/731,632	CROMLISH ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed on 12-15-05, 1-10-06.
2. ☒ The allowed claim(s) is/are 1-7, 11-15, 19 and 22-27.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Manjunath N. Rao, Ph.D.
 Primary Examiner
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DETAILED ACTION

Reissue Application

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-13-05 and 1-10-06 has been entered.

Claims 1-7, 11-15, 19, 22-27 are currently pending in this re-issue application.

Applicants' amendments and arguments filed on 12-13-05 and 1-10-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,543,297 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

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Oath/Declaration

The reissue oath/declaration filed with the amendment filed on 12-13-05 has been considered.

Sequence Compliance

Applicant's response to the sequence compliance rules by way of providing appropriate SEQ ID NOs for sequences depicted in the figures is acknowledged and the corrected drawings have been accepted for examination purposes.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Curtis C. Panzer on 1-31-06.

The application has been amended as follows:

A) Claim 1. (Currently amended) An assay for determining the cyclooxygenase- 2 activity [of a sample] of a composition comprising a human osteosarcoma cell preparation, a sample and arachidonic acid, the assay comprising the steps of:

(a) preparing the composition by adding

(1) [a] the human osteosarcoma cell preparation,

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(2) [a] the sample, said sample comprising a putative cyclooxygenase-2 inhibitor,
and

(3) the arachidonic acid; and

(b) determining the amount of prostaglandin E₂ produced in step (a).

B) Claim 3. (Currently amended) An assay for determining the cyclooxygenase-2 activity of [a sample] a composition comprising a human osteosarcoma cell preparation, a sample and arachidonic acid, the assay comprising the steps of:

(a) preparing the composition by adding

(1) [a] the human osteosarcoma cell preparation,

(2) [a] the sample, said sample comprising a putative cyclooxygenase-2 inhibitor,
and

(3) the arachidonic acid; and

(b) determining the amount of prostaglandin E₂ produced in step (a)

(c) [corrolating] correlating the amount of prostaglandin E₂ produced with
cyclooxygenase-2 activity,

wherein the osteosarcoma cell preparation consists essentially of osteosarcoma 143.98.2
microsomes.

C) Claim 6. (Currently amended) An assay for determining the cyclooxygenase-2 activity of [a sample] a composition comprising a human osteosarcoma cell preparation, a sample and arachidonic acid, the assay comprising the steps of:

(a) preparing the composition by adding

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(1) [a] the human osteosarcoma cell preparation,

(2) [a] the sample, said sample comprising a putative cyclooxygenase-2 inhibitor,
and

(3) the arachidonic acid; and

(b) determining the amount of prostaglandin E₂ produced in step (a),

(c) [corrolating] correlating the amount of prostaglandin E₂ produced with
cyclooxygenase-2 activity,

wherein the human osteosarcoma cell preparation contains no recombinant vector.

D) Claim 7. (Currently amended) An assay for determining the cyclooxygenase-2 activity of
[a sample] a composition comprising a human osteosarcoma cell preparation, a sample and
arachidonic acid, the assay comprising the steps of:

(a) preparing the composition by adding

(1) [a] the human osteosarcoma cell preparation,

(2) [a] the sample, said sample comprising a putative cyclooxygenase-2 inhibitor,
and

(3) the arachidonic acid; and

(b) determining the amount of prostaglandin E₂ produced in step (a)

(c) [corrolating] correlating the amount of prostaglandin E₂ produced with
cyclooxygenase-2 activity,

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wherein the osteosarcoma cell preparation consists essentially of whole cells of osteosarcoma 143.98.2.

E) Claim 11. (Currently amended) An assay for determining the cyclooxygenase-1 activity of [a sample] a composition comprising the steps of:

(a) preparing the composition by adding

(1) a COX-1 cell preparation, wherein the cell preparation consists essentially of whole cells of U-937 or U-937 microsomes,

(2) a sample, said sample comprising a putative cyclooxygenase-1 inhibitor;

(3) arachidonic acid; and

(b) determining the amount of prostaglandin E₂ produced in step (a)

[(c) correlating the amount of prostaglandin E₂ produced with cyclooxygenase-2 activity].

F) Claim 14. (Currently amended) An assay according to claim 11 [for determining the cyclooxygenase-1 activity of a sample according to claim 10 comprising the steps of:

(a) adding

(1) a COX-1 cell preparation,

(2) a sample, said sample comprising a putative cyclooxygenase-1 inhibitor;

(3) arachidonic acid; and

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(b) determining the amount of prostaglandin E₂ produced in step (a),]

wherein the cell preparation comprises 10^5 to 10^8 whole cells of U-937 per cc, or 1 to 10 mg of U-937 microsomes per ml of preparation; and
0.1 to 50 μ l of arachidonic acid per ml of preparation.

G) Claim 19. (Currently amended) [A] An isolated [transformed] host cell that expresses cyclooxygenase-2 [as shown in FIG. 1 (SEQ. ID. NO.10:)] [comprising:] wherein said host cell is transformed with

[(a)] a mammalian or eukaryotic expression vector [; and

(b)] comprising a sequence encoding [human] said cyclooxygenase-2 comprising bases 97 to 1909 of [as shown in FIG. 2 (] SEQ. ID. NO: 11 [)] or encodes [protein of] the polypeptide [FIG. 1 (] SEQ. ID. NO: 10[)].

H) Claim 22. (New) An isolated cyclooxygenase-2 cDNA comprising the coding region which is bases 97 to 1909 of SEQ. ID. NO: 11.

I) Claim 23. (New) A recombinant cyclooxygenase-2 consisting of SEQ. ID. NO: 10.

J) Claim 24. (New) An isolated cyclooxygenase-2 consisting of SEQ. ID. NO: 10.

K) Claim 25. (New) A purified cyclooxygenase-2 consisting of SEQ. ID. NO: 10.

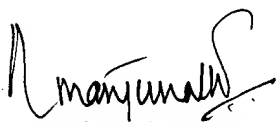
L) Claim 27. (New) The transformed host cells according to claim 19 wherein said host cells are COS-7 cells.

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Allowable Subject Matter

Claims 1-7, 11-15, 19, 22-27 allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

February 14, 2006